

**FAX TRANSMISSION****DATE:** April 5, 2005**PTO IDENTIFIER:** Application Number 09/902,705-Conf. #8314  
Patent Number 6,849,436 B2**Inventor:** Bednarik et al.**MESSAGE TO:** Certificate of Corrections Branch**FAX NUMBER:** (703) 308-6672**FROM:** HUMAN GENOME SCIENCES, INC.

Mark J. Hyman, Reg. No. 46,789

**PHONE:** (240) 314-1224**Attorney Dkt. #:** PF138P1C1**PAGES (Including Cover Sheet):** 12**CONTENTS:**

1. Fax Cover Sheet (1 page);
2. Request for Certificate of Correction (No Fee) (2 pages) with Exhibit A (2 pages) and Exhibit B (5 pages);
3. Proposed Certificate of Correction (1 page); and
4. Certificate of Transmission (1 page)

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**HUMAN GENOME SCIENCES, INC.**

Intellectual Property Dept , 14200 Shady Grove Road, Rockville, Maryland 20850

**Telephone:** **Facsimile:**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Letters Patent of:  
Bednarik et al.

Docket No.: PF138P1C1

Patent No.: 6,849,436 *B2*

Issued: February 1, 2005

For: Human Hypoxanthine-(Guanine) Phosphoribosyl  
Transferase-2

**REQUEST FOR CERTIFICATE OF CORRECTION  
PURSUANT TO 37 CFR 1.322**

MS Post Issue  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Upon reviewing the above-identified patent, Patentees noted typographical errors which should be corrected.

Title Page:

On the Title Page, under the heading "OTHER PUBLICATIONS," in the right-hand column of page 2 at line 6, the following citation should be corrected as follows:

"Genbank Entry Accession No. ~~106859~~ (1994)" should read --Genbank  
Entry Accession No. 106859 (1994)--.

The above-cited reference was listed on Form PTO/SB/08 that accompanied an Information Disclosure Statement filed September 17, 2003, and was initialed by the Examiner and returned to Applicants together with an Office Action mailed December 4, 2003. A copy of the Examiner-initialed Form PTO/SB/08 is submitted herewith as Exhibit A.

In the Claims:

Claim 42, at line 17, should be corrected as follows:

42. An isolated nucleic acid molecule comprising a polynucleotide sequence encoding a polypeptide selected from the group consisting of:

- (a) a polypeptide comprising an amino acid sequence which is at least 95% identical to amino acids 1 to 212 of SEQ ID NO:2; and

APR 06 2005

- (b) a polypeptide comprising an amino acid sequence which is at least 95% identical to the sequence of a polypeptide encoded by the cDNA contained in ATCC Deposit No. ~~75884~~ 75844.

Originally numbered Claim 103 was amended by Examiner's Amendment, allowed, and renumbered as Claim 42, as indicated in the Notice of Allowability mailed September 21, 2004. A copy of the Notice is submitted herewith as Exhibit B.

Transmitted herewith is a proposed Certificate of Correction effecting such amendment. Patentees respectfully solicit the granting of the requested Certificate of Correction.

The above-identified errors were not in the application as filed or amended by applicant; accordingly no fee is believed to be required. However, should the Patent Office determine otherwise, please charge such fee to our Deposit Account No 08-3425.

Dated: April 5, 2005

Respectfully submitted,

By Mark J. Hyman  
Mark J. Hyman

Registration No.: 46,789  
HUMAN GENOME SCIENCES, INC.  
Intellectual Property Dept.  
14200 Shady Grove Road  
Rockville, Maryland 20850  
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APR 06 2005



Approved by the Director of the U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE  
 U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Substitute for 121 in 442A3 PTC		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	09/902,705-Conf. #8314
		Filing Date	July 12, 2001
		First Named Inventor	Daniel P. Bednark
		Art Unit	1652
		Examiner Name	<del>STEADMAN</del> D. RAMIREZ
		Attorney, Doctet Number	PF138P1C1
Sheet	1	of	2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number (Number Field Code, if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
DR	AA	4,749,570	06-07-1988	POZNANKY et al.	
DR	AB	5,108,921	04-28-1992	LOW et al.	
DR	AC	US 09/912,292		ROSEN et al.	Pages 1-75 (pages 1 and 2 partially redacted); portion of Table 2, and SEQ ID NO 23842
DR	AD	5,082,670	01-21-1992	GAGE et al.	
DR	AE	5,118,601	06-02-1992	GRUBER et al.	
DR	AF	RE 34,387	09-21-1993	HOLMES et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials	Cite No.	Foreign Patent Document (Country Code, Number, and Code, if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
DR	AG	WO-94/17183	08-04-1994	BERGMANN et al.	
DR	AH	WO-97/42320	11-13-1997	PAULAKIS et al.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and do not consider. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kinda Codes of USPTO Patent Documents at: ... of MPEP 901.04. \*Enter Office that issued the document by the two-letter code (WIPO Standard ST 3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbol as indicated on the document under WIPO Standard ST 16 if possible. \*Applicant is to place a check mark here if English language translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published			T
DR	AI	OLSEN and MILMAN "Chinese hamster hypoxanthine-guanine phosphoribosyltransferase." J. Biol. Chem. 249(13):4030-4037 (1974)			
DR	AJ	Biochemistry by A. L. Lehninger. Published by Worth Publishers, Inc., 70 Fifth Ave., NY, NY 10011. PP. 109-122.			
	AK	HARPER et al. "Review of Physiological Chemistry." 4th Edition. Lange Medical Publications, Los Angeles, PP. 496-498.			
	AL	BROWN "Gene Therapy: Oversold by Researchers, Journalists." The Washington Post.			
DR	AM	1990 Sigma Chemical Company Catalog. (Published by Sigma Chemical Company, P.O. Box 14508, St. Louis, Missouri). Page 1100			
DR	AN	OLARU et al. "Revue Roumaine De Biochimie." Volume 18, Number 2, pages 131-137 (full document) (1981).			
DR	AO	DAVIDSON et al. "Purine and Pyrimidine Metabolism in Man VII, Part B (Published by Plenum Press New York, New York) pages 1-5-108. (1991).			
DR	AP	MILLER et al. "A transmissible retrovirus expressing human hypoxanthine phosphoribosyltransferase (hprt): gene transfer into cells obtained from humans deficient in hprt." Proc. Natl. Acad. Sci. USA, Aug. 80(15):4709-4713 (1983).			
DR	AO	PALELLA et al. "Expression of human hprt mRNA in brains of mice infected with a recombinant herpes simplex virus-1 vector." Gene. 80(1) 137-144 (1989).			
DR	AR	ANDERSON W F. "Prospects for human gene therapy." Science. 226, 401-409 (1984).			

Examiner Signature	Delia Ramirez	Date Considered	11/12/03
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EXHIBIT A



Under the Paperwork Reduction Act of 1995, no person shall be required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1-49A-B-PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1

2

of

2

### Complete if Known

Application Number	09/902,705-Conf #8314
Filing Date	July 12, 2001
First named inventor	Daniel P. Bednarek
Art Unit	1652
Examiner Name	<del>Shannon D</del> RAMIREZ
Attorney Docket Number	PF138P1C1

AS	GHANGAS and MILMAN. "Radioimmuno determination of hypoxanthine phosphoribosyltransferase crossreacting material in erythrocytes of Lesch-Nyhan patients." Proc Natl Acad Sci USA. 72(10):4147-4150. (1975)
AT	MELTON et al. "Structure, expression, and mutation of the hypoxanthine phosphoribosyltransferase gene." Proc. Natl. Acad. Sci. USA. 81:2147-2151 (1984).
AU	JOLLY et al. "Isolation and characterization of a full-length expressible cDNA for human hypoxanthine phosphoribosyl transferase." Proc Natl. Acad. Sci. USA 80:477-481. (1983)
AV	PATEL et al. "Organization of the HPRT gene and related sequences in the human genome." Somatic Cell and Molecular Genetics. 10(5):483-493 (1984)
AW	SCULLEY et al. "A review of the molecular basis of the hypoxanthine-guanine phosphoribosyltransferase (HPRT) deficiency." Hum. Genet. 90:195-207 (1992)
AX	YIP and BALIS. "Polyamine-polyphosphate complexes as enzyme inhibitors." Biochemistry. 19:1849-1856 (1980)
AY	YUAN et al. "Steady-state kinetics of the schistosomal hypoxanthine-guanine phosphoribosyltransferase." Biochemistry. 31:806-810. (1992)
AZ	WU and MELTON. "Production of a model for Lesch-Nyhan syndrome in hypoxanthine phosphoribosyltransferase-deficient mice." Nature Genetics. 3:235-240. (1993)
BA	Genbank Entry Accession No. T00169 (1992)
BB	Genbank Entry Accession No. T00115 (1992)
BC	Genbank Entry Accession No. T23947 (1994)
BD	Genbank Entry Accession No. T24112 (1994)
BE	Genbank Entry Accession No. T24119 (1994)
BF	Genbank Entry Accession No. T00696 (1992)
BG	Genbank Entry Accession No. T11051 (1993)
BH	Genbank Entry Accession No. T02687 (1993)
BI	Genbank Entry Accession No. T00217 (1992)
BJ	Genbank Entry Accession No. T00154 (1992)
BK	Genbank Entry Accession No. Z47172 (1995)
BL	Genbank Entry Accession No. L25928 (1993)
BM	Genbank Entry Accession No. L26978 (1995)
BN	Genbank Entry Accession No. A20700 (1994)
BO	Genbank Entry Accession No. A20702 (1994)
BP	Genbank Entry Accession No. J06859 (1994)
BQ	Genbank Entry Accession No. L25927 (1993)
BR	HASSETT et al. "Characterization of cDNA clones encoding rabbit and human serum paraoxonase: the mature protein retains its signal sequence." Biochemistry. 30(42):10141-10149. (1991)
BS	ADKINS et al. "Molecular basis for the polymorphic forms of human serum paraoxonase/arylesterase: glutamine or arginine at position 191, for the respective A or B alleles." Am. J. Hum. Genet. 52:598-608 (1993)
BT	JOHNSON et al. Biological Abstracts. 69(7):4678 (1980)

\*EXAMINER: Indicate if reference considered whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*APPLICANT: Indicate unique citation designation number (optional). \*APPLICANT: Indicate a check mark here if English language Translation is attached.

Examiner Signature	Delia Ramirez	Date Considered	11/12/03
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**Notice of Allowability****Application No.**

09/902,705

**Examiner**

Delia M. Ramirez

**Applicant(s)**

BEDNARIK ET AL.

**Art Unit**

1652

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—  
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/16/2004.
2. ☒ The allowed claim(s) is/are 27-29, 31, 33-37, 64-66, 68, 70-74, 77-81, 84-95, 97, 98-105, 108-114.
3. ☒ The drawings filed on 22 March 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                 | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

Application/Control Number: 09/902,705  
Art Unit: 1652

Page 2

### DETAILED ACTION

#### *Status of the Application*

Claims 27-31, 33-37, 64-68, 70-81, 84-114 are pending.

Amendment of claims 27-29, 64-66, 77-81, 91-95, 103-107, and cancellation of claims 82-83, 115-126 in a communication filed on 8/16/2004 is acknowledged.

In a telephone conversation with Melissa Pytel on 9/8/2004, an agreement was reached to amend claims 31, 68, 97, 103, and cancel claims 30, 67, 75-76, 96, 106-107 to place the application in condition for allowance.

#### *Examiner's Amendment*

1. An informal Examiner's amendment to the specification appears below. This amendment is to update the status of prior application(s) to which priority is claimed in the first sentence of the specification (37 CFR 1.78).

2. Please enter the following amendments to the specification as follows:

3. In page 1, please replace paragraph [001] with the following paragraph:

This application is a continuation of and claims priority under 35 U.S.C. § 120 to U.S. Application No. 08/461,031, filed June 5, 1995, now abandoned, which is a continuation-in-part of and claims priority under 35 U.S.C. § 120 to International Application No. PCT/US94/11914, filed on October 19, 1994, (which International Application was published by the International Bureau in the English language on May 2, 1996 as International Publication No. WO 96/12501), both of which are hereby incorporated by reference in their entirety.

4. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Application/Control Number: 09/902,705

Page 3

Art Unit: 1652

5. Authorization for this Examiner's amendment was given in a telephone interview with Melissa Pytel on 9/8/2004.

6. Please cancel claims 30, 67, 75-76, 96, 106-107.

7. Please replace claims 31, 68, 97, 103 as follows:

31. An isolated nucleic acid molecule consisting of at least 50 contiguous nucleotides of nucleotides 626 to 1260 of SEQ ID NO: 1, or the completely complementary strand thereto, wherein said isolated nucleic acid is linked to a heterologous polynucleotide encoding a heterologous polypeptide.

68. An isolated nucleic acid molecule consisting of at least 50 contiguous nucleotides of the coding sequence of the human cDNA contained in ATCC Deposit No. 75844, or the completely complementary strand thereto, wherein said isolated nucleic acid is linked to a heterologous polynucleotide encoding a heterologous polypeptide.

97. An isolated nucleic acid molecule consisting of a polynucleotide sequence encoding a polypeptide selected from the group consisting of:

(a) a polypeptide consisting of at least 30 contiguous amino acid residues of amino acids 1 to 212 of SEQ ID NO: 2;

(b) a polypeptide consisting of at least 50 contiguous amino acid residues of amino acids 1 to 212 of SEQ ID NO: 2;

(c) a polypeptide consisting of at least 30 contiguous amino acid residues of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844; and

(d) a polypeptide consisting of at least 50 contiguous amino acid residues of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844;

wherein said isolated nucleic acid is linked to a heterologous polynucleotide encoding a heterologous polypeptide.



Application/Control Number: 09/902,705

Page 4

Art Unit: 1652

103. An isolated nucleic acid molecule comprising a polynucleotide sequence encoding a polypeptide selected from the group consisting of:

(a) a polypeptide comprising an amino acid sequence which is at least 95% identical to amino acids 1 to 212 of SEQ ID NO: 2; and

(b) a polypeptide comprising an amino acid sequence which is at least 95% identical to the sequence of a polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844.

*Reasons for Allowance*

8. The following is an Examiner's statement of reasons for allowance. Although the prior art discloses nucleic acids encoding hypoxanthine (guanine) phosphoribosyl transferases, the Examiner has found no teaching or suggestion in the prior art directed to the polynucleotide of SEQ ID NO:1 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Therefore, claims 27-29, 31, 33-37, 64-66, 68, 70-74, 77-81, 84-95, 97-105, 108-114 directed to the polynucleotide of SEQ ID NO: 1, a polynucleotide encoding the polypeptide of SEQ ID NO: 2, fragments of said polynucleotides, structural homologs of said polynucleotides encoding a hypoxanthine (guanine) phosphoribosyl transferase 2, vectors, host cells, and a method to recombinantly produce the polypeptide of SEQ ID NO: 2, fragments thereof, and structural homologs of the polypeptide of SEQ ID NO: 2 having hypoxanthine (guanine) phosphoribosyl transferase 2 activity, are allowable over the prior art of record.

9. Claims 27-29, 31, 33-37, 64-66, 68, 70-74, 77-81, 84-95, 97-105, 108-114 are allowed.

10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

Application/Control Number: 09/902,705

Page 5

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
September 9, 2004

*Delia M. Ramirez*  
1652

PTO/SB/44 (04-04)

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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(Also Form PTO-1050)**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO . 6,849,436 *B2*  
DATED . February 1, 2005  
INVENTOR(S) : Bednarik et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page:

Item [56], References Cited, under the heading "OTHER PUBLICATIONS," in the right-hand column of page 2, please replace item 6 with the following:

--Genbank Entry Accession No. I06859 (1994)--

In the Claims:

Please replace Claim 42 with the following:

42. An isolated nucleic acid molecule comprising a polynucleotide sequence encoding a polypeptide selected from the group consisting of:

- (a) a polypeptide comprising an amino acid sequence which is at least 95% identical to amino acids 1 to 212 of SEQ ID NO.2; and
- (b) a polypeptide comprising an amino acid sequence which is at least 95% identical to the sequence of a polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844.

**MAILING ADDRESS OF SENDER:**

Mark J Hyman  
HUMAN GENOME SCIENCES, INC.  
Intellectual Property Dept.  
14200 Shady Grove Road  
Rockville, Maryland 20850

**PATENT NO. 6,849,436 *B2***

No. of additional copies 0

**APR 06 2005**

PTO/SB/97 (09-04)

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Application No (if known): 09/902,705

Attorney Docket No.: PF138P1C1

**Certificate of Transmission under 37 CFR 1.8**

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on April 5, 2005  
Date

*Mark J. Hyman*  
Signature

Mark J. Hyman

Typed or printed name of person signing Certificate

46,789

Registration Number, if applicable

(240) 314-1224

Telephone Number

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1. Fax Cover Sheet (1 page);
2. Request for Certificate of Correction (No Fee) (2 pages) with Exhibit A (2 pages) and Exhibit B (5 pages);
3. Proposed Certificate of Correction (1 page); and
4. Certificate of Transmission (1 page)